

**REMARKS**

Claims 1-24, 26, 27 and 29 are pending in the present Application. Claims 1, 13, 20, 22, 24, 26 and 29 are written in independent form. Claims 25, 28 and 30 were previously cancelled. Claims 1, 13, 20, 22, 24, 26 and 29 are amended. No new matter is added.

**I. Claim Objections:**

Claim 26 is objected to because the phrase “control unit **an** said interface unit” in line 3 of the claim is believed to be a typographical error for “control unit and interface unit.” As claim 26 is amended to overcome the objection, withdrawal of the objection is requested.

**II. Rejection under 35 USC §112:**

Claims 20 and 21 are rejected under 35 USC §112, second paragraph, for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter Applicant regards as the invention.

Claim 20 is amended to overcome the rejection. As such, withdrawal of the rejection of claim 20 and dependent claim 21 is requested.

It is further alleged that the specification fails to link or associate the disclosed structure such that one of ordinary skill in the art would recognize what structure, materials or acts perform the claimed function of “means for communication between said control unit and said interface unit” and “means for simulating an effect of a first instrument inserted into a second instrument,” as recited for example in claim 20.

Applicants refer the Examiner to paragraph [0016] of the specification which describes a digitized communication instruction set for communication between the

control unit (e.g., computer unit 110) and the interface unit (e.g., 120). As described at paragraph [0032] for example, the apparatus 100 includes a computer unit 100 and an interface device 120. The computer unit 110 may be a conventional PC or similar, or a unit integrated with the interface device 120. Thus, one of skill in the art would readily understand that the digitized communication instruction set for communication between the control unit and the interface unit may be the structure, materials or acts that perform the claimed function (see also claims 24 and 25).

Regarding the allegation that the specification fails to link or associate the disclosed structure such that one of ordinary skill in the art would recognize what structure, materials or acts perform the claimed function of the claimed “means for simulating an effect of a first instrument inserted into a second instrument,” Applicants respectfully remind the Examiner that the claimed subject matter is disclosed in the specification as being “best realized as a computer program and that the program may include a first instruction set for simulating handling of a number of simulated instruments simultaneously interfaced by the interface unit (paragraph [0013]). According to the specification, both real and dummy instruments may be used, and the instruments are simulated assuming that they interact nested, i.e., inserted into each other (paragraph [0009]). According to the specification, a method for simulating an interventional procedure may include simulating the instruments assuming that they are nested, i.e., inserted into each other (paragraph [0011]).

Thus, one of skill in the art would readily understand that the “means for simulating an effect of a first instrument inserted into a second instrument,” may be an instruction set of a computer program as described throughout the present specification (see also paragraphs [0013], [0016], [0034], [0035], [0046] and [0097]. Thus, the specification does link or associate the disclosed structure such that one of ordinary

skill in the art would recognize what structure, materials or acts perform the claimed function of the claimed “means for simulating an effect of a first instrument inserted into a second instrument.” Accordingly, withdrawal of the rejection is requested.

### **III. Rejection under 35 USC §102:**

Claim 24 is rejected under 35 USC §102(e) as being unpatentable over US Patent Application Publication 2002/0168618 to Anderson et al. (“Anderson”). The rejection is respectfully traversed.

Independent claim 24 is amended to recite that the interface unit has a plurality of carriages, and that program comprises a fourth instruction set for generating control signals relating to an interaction between the simulated nested instruments and a surrounding geometry relating to a part of said simulated body part, each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic, a detecting arrangement for detecting the type of the instruments inserted through a interconnecting member, means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator, a crank block, arranged on a torque wheel, an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage, said detecting member being arranged to detect the thickness of each instrument.

Anderson relates to a system and method for computer simulation of image-guided diagnostic and therapeutic procedures. It is alleged in the Office Action that Anderson discloses a control unit and an interface unit at Fig. 4. Fig. 4 shows a CPU (assumed to be intended by the Examiner to correspond to the claimed control unit) and

“various system inputs...such as touch screens, footswitches, syringes, C-arm, hand-operated balloon device, feedback structures, and their connections with a system processor” (paragraph [0043]). However, none of the various system inputs shown in Fig. 4 are carriages as recited in claim 24 as amended. Accordingly, Anderson does not disclose or suggest a computer readable medium that includes an instruction set for controlling such carriages. Therefore, withdrawal of the rejection is requested.

Claim 29 is rejected under 35 USC §102(e) as being unpatentable over US Patent 6,929,481 to Alexander et al. (Alexander). The rejection is respectfully traversed.

Independent claim 29 is amended to recite that the method of an interventional procedure training includes using a real nested interventional procedure tool, including a first tool inserted into a second tool to be simulated in said interface device, and that the interface unit includes a plurality of carriages, each carriage comprising members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic, a detecting arrangement for detecting the type of the instruments inserted through a interconnecting member, means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage, said detecting member being arranged to detect the thickness of each instrument.

Alexander relates to an interface device and method for interfacing instruments to a medical procedure simulation system that serve to interface mock medical instruments with a computer system to simulate medical procedures. The interface

device 314 of Alexander may be configured to measure motion of a plurality of instruments at their respective distal tips, and enable the instruments to be exchanged in any desired order during a simulated procedure as illustrated in FIG. 9. As shown in Fig. 9, the interface device 314 accommodates a wire 302 optionally having a handle 308, an actual or mock catheter 304 optionally having a handle 310, and an actual or mock sheath 306 optionally having a handle 312. The interface device measures manipulation of the wire, catheter and sheath, and provides signals indicating the measured manipulation to computer system 25 via communications interface 24.

However, there is no description or suggestion in Alexander of an interface having a detecting arrangement for detecting the type of the instruments inserted through a interconnecting member, means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage, said detecting member being arranged to detect the thickness of each instrument.

Because Alexander fails to disclose or suggest all of the features recited in the claim as amended, withdrawal of the rejection is requested.

#### **IV. Rejection under 35 USC §103:**

Claims 1-23, 26, and 27 are rejected under 35 USC §103(a) as being unpatentable over Anderson in view of Alexander.

Independent claims 1, 13, 20, 22, 24, 26 and 29 are amended to recite that each carriage comprises members to receive and lock at least one of the instruments, and members for receiving a movement from the instrument dummy and generating a force fed back to the instrument dummy with respect to a simulation characteristic, a

detecting arrangement for detecting the type of the instruments inserted through a interconnecting member, means to provide the movement of each carriage and regulate the movement by means of a speed regulator and a distance regulator, a crank block, arranged on a torque wheel, and an outlet, which is provided with a detecting member, configured to detect presence of at least one instrument in the carriage, said detecting member being arranged to detect the thickness of each instrument.

As discussed above when considered separately neither Anderson nor Alexander disclose or suggest the features of the amended claims. Because neither of the references separately discloses or suggests the claim features, the combination of references cannot disclose or suggest those features. For example, even though Alexander discloses an interface device 314 that measures motion of a plurality of instruments at their respective distal tips, Alexander fails to disclose the carriages as claimed. As Anderson is silent regarding a carriage or carriages, Anderson does not overcome the deficiencies of Alexander. Therefore, the combination of references fails to render the rejected claims, as amended, obvious. Withdrawal of the rejection is requested.

### **CONCLUSION**

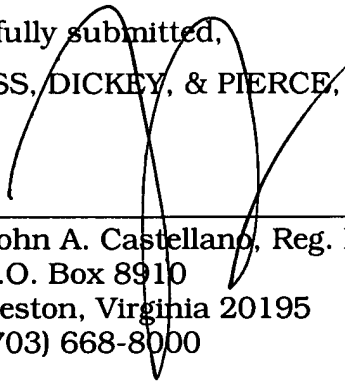
In view of the above, Applicant earnestly solicits reconsideration and allowance of all of the pending claims.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-

0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17;  
particularly, extension of time fees.

Respectfully submitted,  
HARNESS, DICKY, & PIERCE, P.L.C.

By:   
John A. Castellano, Reg. No. 35,094  
P.O. Box 8910  
Reston, Virginia 20195  
(703) 668-8000

JAC/JWF:eaf  
